OCT 1 6 2001

K012346

510(k) Summary of Safety & Effectiveness

Submitter

Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, FL 33815

Contact

Mr. Mike Sammon, Ph.D.
Director, Research and Development
(863) 683-8680, extension 228
(801) 327-3339 (facsimile)
mikes@safe-reuse.com

Date

July 20, 2001

Device

- Trade Names: Vanguard Reprocessed Arthroscopic Blades
  - ⇒ Dyonics® Arthroscopic Blades
  - ⇒ Stryker® Arthroscopic Blades
  - ⇒ Linvatec Arthroscopic Blades
- Common Name: Arthroscopic blades, shaver or burr
- Classification: 21 CFR 888.1100 – Arthroscope – Class II
- Product Code HRX

Predicate Devices

Respective Dyonics®, Stryker® and Linvatec legally marketed arthroscopic blades under various 510(k) premarket notifications.

Indications for Use

An arthroscopic blade is indicated for resection of soft and osseous tissues in articular cavities. Use of the device within paranasal sinuses (Funtional Endoscopic Sinus Surgery [FESS]) is limited to appropriately small blades (3.5 mm).

Contra-indications

- Arthroscopic blades should not be used in patients exhibiting ankylosis, with inadequate joint space or distension for arthroscopic inspection.
- Abrasion arthroplasty may not be effective in treating heavy patients.

Continued on next page

510(k) Summary of Safety & Effectiveness, Continued

Contra-Indications, continued

- Intracortical abrasion arthroplasty may be contraindicated in patients not qualifying for high tibial osteotomy or total knee replacement.
- Synovectomy is contraindicated when the disease has progressed beyond synovial proliferation, and when erosion of the articular cartilage is present with advanced rheumatoid arthritis.

Device Description

Arthroscopic blades, when coupled with a compatible arthroscopic hand-piece and motorized control console, are used to resect soft and osseous tissue in articular cavities.

An arthroscopic blade is designed as a "tube within a tube". A smaller diameter inner sleeve rotates within a larger diameter outer sleeve. The outer diameter and contour of the inner sleeve closely matches the inner diameter and contour of the outer sleeve. The distal end of the outer sleeve has an approximately half-diameter cut-out that acts as a hold and shearing edge for the cutting action of the inner sleeve.

Depending upon the model, the distal end of the inner sleeve is commonly referred to as a shaver or burr. The distal tip of a shaver inner sleeve has a half-diameter cut-out with sharpened edges or serrated teeth and is designed for cutting tissue. The distal tip of a burr inner sleeve is a series of axially elongated, inclined cutting edges ("flutes") space circumferentially around the distal tip and is typically used for abrading bone.

At their proximal ends, both sleeves are mounted within molded plastic hubs that couple with the hand-piece of their compatible programmable motorized control console ("drive unit"). Neither the hand-piece nor the drive unit is reprocessed by Vanguard.

Continued on next page

510(k) Summary of Safety & Effectiveness, Continued

Device Description, continued

The outer sleeve hub is designed to engage and lock into the OEM proprietary motorized hand-piece and to provide a water tight seal with the hand-piece housing. Depending upon the OEM, the seal is provided by an elastomeric sealing ring installed on the hub or in the hand-piece housing. The inner sleeve hub is designed to rotationally engage the shaft coupling of the hand-piece motor and to provide means for spring-loading the distal end of the inner sleeve against the distal end of the outer sleeve. The inner sleeve hub has an open port to the proximal end that connects with a fluid line in the hand-piece. This allows fluid to be aspirated from the surgical site through the inner rotating sleeve. The fluid, typically and isotonic saline solution, is intended to remove severed tissue and to cool/lubricate the distal cutting ends of the arthroscopic blade.

The drive unit may run clockwise, counter-clockwise or in an oscillatory mode, typically at 100 – 3000 rpm in the uni-directional mode and up to 1500 rpm in the oscillatory mode.

Vanguard receives previously used arthroscopic shavers, burrs and blades from healthcare facilities; cleans, refurbishes (if necessary, sharpens), inspects, tests, repackages and sterilizes the devices; and returns them to the healthcare facility.

Technological Characteristics

The Vanguard reprocessed arthroscopic blades are essentially identical to the currently marketed OEM blades. No changes are made to the currently marketed device's specifications and they possess the same technological characteristics. Biocompatibility, pyrogenicity and performance/functional testing demonstrate that the devices are equivalent and continue to be safe and effective for their intended use.

Test Data

Sterilization and packaging validations, and functional/performance, pyrogenicity and biocompatibility testing demonstrates that the reprocessed devices perform as intended and are safe and effective.

Continued on next page

510(k) Summary of Safety & Effectiveness, Continued

Conclusion

Based on the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that the Vanguard reprocessed arthroscopic blades are substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 6 2001

Mike Sammon, Ph.D.
Director, Research and Development
Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, Florida 33815

Re: K012346
Trade/Device Name: Vanguard Reprocessed Arthroscopic Blades
Regulation Number: 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: July 20, 2001
Received: July 24, 2001

Dear Dr. Sammon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker, MD

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K072346

Device Name: Vanguard Reprocessed Arthroscopic Blades

Indications for Use:

An arthroscopic blade is indicated for resection of soft and osseous tissues in articular cavities. Use of the device within paranasal sinuses (Funtional Endoscopic Sinus Surgery [FESS]) is limited to appropriately small blades (3.5 mm).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012346